

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

ERIC L. JEFFRIES,	:	
	:	Case No. C-1-02-351
Plaintiff,	:	
	:	(Judge Beckwith)
vs.	:	(Magistrate Judge Hogan)
	:	
CENTRE LIFE INSURANCE COMPANY,	:	<u>DAUBERT MOTION AND</u>
et al.,	:	<u>MEMORANDUM IN SUPPORT TO</u>
	:	<u>EXCLUDE TESTIMONY BASED</u>
Defendants.	:	<u>ON PET AND SPECT SCANS</u>

Now comes Defendant Centre Life Insurance Company and moves to exclude the testimony of Dr. Pretorius and Dr. Hyde pursuant to the mandate of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786 (1993). Their testimony is not reliable nor scientifically valid.

Respectfully submitted,

s/Peter M. Burrell

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MEMORANDUM IN SUPPORT

I. INTRODUCTION

Defendants move to exclude the reports of Drs. Pretorius and Hyde and any proffered testimony to the extent they rely upon use of PET and SPECT scans for incorrect diagnostic purposes. Plaintiff has identified Harold T. Pretorius and Byron Hyde as potential expert witnesses. Defendant has deposed both in an attempt to determine whether any scientific basis for their opinions exist.

Dr. Pretorius has offered a report based on his review of SPECT scans he performed on Mr. Jeffries. In particular, Dr. Pretorius has offered the opinion that he can tell based on review of the scans that Mr. Jeffries does not have obsessive compulsive disorder or somatiform disorder or any other psychological disorder. He also claims that based on the SPECT scans he can diagnose Mr. Jeffries with a physical problem, specifically, inflammation of the brain caused by Mr. Jeffries' Hepatitis B inoculation. Dr. Pretorius' reliance on PET and SPECT scans for the inclusion or exclusion of these diagnoses is improper and not reliable testimony in the medical community. Dr. Hyde also relies on PET and SPECT scans to some degree in his diagnosis although he admits in his deposition that such reliance has not been scientifically accepted. To the extent that these physicians have offered speculative opinions which are not medically reliable, their testimony must be excluded under *Daubert*.

II. ARGUMENT

A. The Opinions Of Dr. Pretorius And Dr. Hyde Are Not Admissible Under Daubert.

The Daubert gate-keeping requirement requires that the testimony of an expert witness be both relevant and reliable. In addressing the admissibility of proposed expert testimony, the Supreme Court has explained that such testimony must "be supported by appropriate

validation -- i.e., ‘good grounds,’ based on what is known” and it must be relevant and helpful to the trier of fact. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590-91, 113 S. Ct. 2786. “Expert testimony which does not relate to any issue in the case is not relevant and, ergo, not helpful.” *See id.* at 591, *citing* 3 Weinstein and Burger, pp. 702-18. The trial judge’s responsibility to admit only expert witness testimony that is both reliable and relevant has been referred to as the “*Daubert* gate-keeping requirement.” As the Supreme Court has recognized:

The objective of that [gate-keeping] requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.

See Kumho Tire Company Limited v. Carmichael, 527 U.S. 137, 119 S. Ct. 1167, 1176 (1999).

Acknowledging that the rules of evidence permit wide latitude for the admissibility of relevant evidence, the United States Supreme Court nonetheless recognized that Rule 702 “clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify.” *See Daubert*, 509 U.S. at 589. An expert may not simply put forth conclusory opinions or restate the arguments of counsel or the claimant under the guise of an expert opinion. As stated by the courts, the word “knowledge” as used in Rule 702 “connotes more than subjective belief or unsupported speculation.” *See id.* at p. 590. The dual requirements of reliability and relevance are appropriate considering the potential, and sometimes disproportionate, impact of expert testimony on the trier of fact. The Supreme Court has stated:

Rule 702’s “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility. That these requirements are embodied in Rule 702 is not surprising. Unlike an ordinary witness, . . . an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation. . . . Presumably, this relaxation of the usual requirement of firsthand knowledge -- a rule which represents a “most pervasive

manifestation” of the common law insistence upon “most reliable sources of information” . . . is premised on an assumption that the expert’s opinion will have a reliable basis in the knowledge and experience of his discipline.

See id. at 592 (internal citations omitted).

This requirement of reliability applies not only to experts offering testimony on scientific matters, as was the issue addressed in *Daubert*, but to all experts who purport to possess “knowledge” helpful to the trier of fact. *See Kumho Tire*, 19 S. Ct. at 1173. It is the duty of the court to evaluate and determine whether the proffered evidence is both relevant and reliable.

When assessing reliability, a court must consider the following factors: (1) Whether the concept has been tested; (2) whether the concept has been subject to peer review; (3) what the known rate of error is; and (4) whether the concept is generally accepted by the community. *See id.* Although the Supreme Court has recognized that not every factor will apply in every case, these are all factors to be considered. *See Kumho Tire*, 119 S. Ct. at 1171.

B. The Opinion Of Dr. Pretorius Is Not Reliable

Dr. Pretorius has expressed the opinion that he can review the SPECT scans conducted on Mr. Jeffries and determine that he has a brain inflammation (cerebritis). *See* Exhibit A, Pretorius depo. at p. 53. Dr. Pretorius has more specifically diagnosed Mr. Jeffries with immune cerebritis in apparent acceptance of Mr. Jeffries’ claim that he suffers an autoimmune disorder caused by his Hepatitis B vaccination. As a threshold matter, SPECT scans cannot be relied upon to diagnose a cerebritis. *See* Exhibit B. Moreover, Dr. Pretorius admitted in his deposition that he cannot differentiate as to the type of cerebritis by the scans. He was questioned:

Q: Does that mean you can or can’t say with specificity, supported by scientific research, that this is immune cerebritis, as opposed to any other cerebritis?

A: I don’t think you can differentiate 100 percent.

Id. at 56.

Even if Dr. Pretorius' diagnosis of cerebritis is accepted on its face which is not scientifically supported, he admits that the diagnosis cannot answer the causation question posed by Mr. Jeffries. Mr. Jeffries argues that his disability was physically caused by his Hepatitis B shot. Dr. Pretorius tries to reiterate this argument. From a medically-reliable standpoint however, he cannot opine as to the cause of Mr. Jeffries' cerebritis or that he even has a cerebritis.

Dr. Pretorius has opined in his report that the SPECT scan tells him that Mr. Jeffries does not have depression, obsessive compulsive disorder, or somatization disorder. The use of PET and SPECT imaging studies is inappropriate and ineffective for the evaluation of psychiatric diagnoses. In deposition, Dr. Pretorius acknowledged that there is little, if any, scientific data that supports his conclusions and that his reliance on the SPECT cans is not generally accepted in the medical community. He also admitted that his testing protocol and mathematical evaluation are not used by other professionals who practice nuclear medicine.

The Sixth Circuit has acknowledged that the factors of the *Kuhmo Tire* test must be considered when assessing the reliability of an expert opinion. *See Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). These factors include: (1) whether the concept has been tested; (2) whether the concept has been subject to peer review; (3) what the known rate of error is, and (4) whether the concept is generally accepted by the community. In this case, three of the four factors can be definitively answered in opposition to allowing SPECT scans. The use of SPECT scans as a diagnostic tool for psychiatric diseases has in fact been considered, subjected to peer review and has been rejected. The concept is not one that is generally accepted by the medical community. Dr. Pretorius acknowledged in deposition that his use of SPECT scans in this manner is not published.

Dr. Pretorius performed two separate scans using two separate isotopes with a single camera. *See* Exhibit A, Pretorius depo. at p. 18. He admitted that this is not a standard protocol for nuclear medicine. *Id.* at p. 35. He admits that his methods and interpretations are unique to him. *Id.* at 42, 49. Although he has attempted to publish his methods, he admits that it “hasn’t caught on.” *Id.*

Finally, he admits that there is no medical literature which supports the use of PET and SPECT scans to diagnose CFS and that there are no established patterns that could diagnose or rule out somatoform disorder. *Id.* at 27, 48. Although he argues that there are suspected patterns consistent with obsessive/compulsive disorder, and he admits that this pattern can be seen on the scans performed on Mr. Jeffries at the University of California, Irvine. *Id.* at 48. Dr. Pretorius’ opinion is not reliable and not medically supported.

C. The Medical Community Does Not Accept SPECT Scans To Diagnose Immune Cerebritis.

Dr. Kirk Frey, M.D., Ph.D. is a staff physician and professor in the Radiology and Neurology departments at the University of Michigan, Ann Arbor, Michigan. *See* Dr. Frey’s report attached hereto as Exhibit B. He is also a research professor in The Mental Health Research Institute at University of Michigan. As a professor at the University of Michigan Medical Center, Dr. Frey supervises and teaches medical students, residents and fellows in the use and interpretation of nuclear medicine procedures including brain PET and SPECT scanning. He has also served as a consultant to U.S. committees on the use of PET and SPECT scans. His Curriculum Vitae is attached to his report as attachment 1. Dr. Frey is familiar with the current standards of care and practice regarding the clinical uses of brain imaging.

It is generally accepted in the nuclear medicine community that PET and SPECT brain imaging can be established diagnostic procedures in a limited number of clinical studies. *See* Exhibit B, Frey report at paragraph 7.

In many of these, the imaging procedure is not able to independently establish a diagnosis, but rather, serves to refine and establish clinical diagnosis made unequivocally on the basis of other information. There are presently no data upon which to rely in the use or interpretation of clinical PET or SPECT imaging procedures for diagnosis of immune cerebritis, cerebral vasculitis, chronic fatigue syndrome, depression, obsessive compulsive disorder or somatization disorder.

See id. at paragraph 7. Dr. Pretorius' reliance on his SPECT scans to diagnose immune cerebritis and exclude the psychological diagnoses is misplaced.

It is important to note that Defendants are not arguing that the PET and SPECT scans in fact show that Mr. Jeffries has somatization disorder or depression or obsessive compulsive disorder. These diagnoses are established by the neurological testing performed by Dr. Hartings and the clinical evaluation of Mr. Jeffries. Dr. Pretorius however, has offered the opinion that his review of the SPECT scans he performed on Mr. Jeffries can be used to establish that Mr. Jeffries does not have these disorders. This is an improper use of PET and SPECT scans. The opinion that SPECT scans cannot be used to rule out these diagnoses is not limited to Dr. Frey, but is in fact "shared by national panels of experts in nuclear medicine and neurology." *See* Frey Report at Paragraph 8.

A recent publication in The Journal of Nuclear Medicine ("Ethical clinical practice of functional brain imaging, "The Journal of Nuclear Medicine, 37: 1256-1259, 1996; Attachment II) also indicates a lack of established diagnostic criteria for immune cerebritis effects in brain FDG PET or cerebral perfusion SPECT scans. It further states that: "...while research SPECT and PET studies in patients with mild traumatic brain injury, substance abuse, infectious diseases states (such as HIV-related encephalopathies), neurotoxic exposures, environmental illness and foreign body reaction show promise, there is not, as of this writing, adequate evidence to support the use of PET or SPECT in these instances to establish cause-and-effect relationships."

Regarding the use of SPECT brain perfusion studies in forensic settings, the authors state: “When there are few controlled experimental studies and no available sensitivity and specificity rates, the forensic application of non-replicated, unpublished or anecdotal SPECT or PET observations is inappropriate and has ominous implications. This can lead to unsupportable conclusions if introduced as ‘objective evidence’ linking neuropsychologic parameters (such as blood flow or metabolism) to a defendant’s judgment, insight, or motives associated with the commission of a crime, or as an ‘offer of proof’ of a traumatically caused or substance-induced illness or injury”.

See Frey Report at Paragraph 8. As the reports cited by Dr. Frey makes clear, although PET and SPECT scans may be used in the management of patients with certain disorders such as stroke, epilepsy, brain tumors and dementia, the use of PET and SPECT scans to diagnose neurological, psychiatric or behavioral deficit is not generally accepted. This report is a culmination of the opinions of numerous committee members from many medical institutions.

As a threshold manner, Dr. Pretorius did not meet the recommended operational guidelines from the committee with regard to the scan procedures. Dr. Frey reviewed the brain scans conducted on Mr. Jeffries and concluded that there was “no scientific basis for performing any of these imaging tests to evaluate or diagnose immune cerebritis (encephalomyelitis), vasculitis, or chronic fatigue syndrome.” *See* Frey Report at Paragraph 9. This is because there are no commonly accepted and uniform scan patterns that can be used in the interpretation.

“Specifically, there are no scientific reports to establish a reliable or specific abnormality or pattern of abnormality in patients with proven diagnoses of these conditions. The presence (or absence) of any findings in these PET and SPECT brain imaging tests, thus, has no bearing on the presence (or absence) of these disorders. Furthermore, the brain PET and SPECT imaging tests are not established scientifically as valid diagnostic tools for presence of depression, obsessive compulsive disorder or somatization disorder. Accordingly, the use of PET or SPECT imaging studies is inappropriate and ineffective for the evaluation of these psychiatric diagnoses.”

See Frey Report at ¶ 9.

In deposition, Dr. Pretorius was given an opportunity to identify any other medical practitioners who have accepted the use of PET and SPECT scans for the diagnosis or exclusion of chronic fatigue syndrome, depression, obsessive compulsive disorder and/or somatiform disorder. He was unable to do so. He also expressed surprise that the Journal of Nuclear Medicine had not accepted his submitted report. Clearly, this is because the committee members hold an alternate view. The article attached to Dr. Frey's report unequivocally rejects Dr. Pretorius' theory. This alternate view is the one more widely accepted. Although PET and SPECT scans may be used for some diagnostic purposes; the use of PET and SPECT scans to diagnose or exclude psychiatric disorders is not one of them.

Dr. Pretorius' report must be excluded. It is scientifically unreliable, it has been subject to peer review and rejected and his methodology is not generally accepted in the medical community. Dr. Pretorius acknowledges as much. When asked to offer support for his opinion, he was unable to do so. As a report of Dr. Frey makes clear, and is supported by the Journal of Nuclear Medicine, the use of PET and SPECT scans in psychiatric diagnosis is inappropriate. Under the test articulated in *Daubert*, therefore, Dr. Pretorius' opinion must be excluded as unreliable. The impact of an expert witnesses' testimony can be disproportionately large. Where the expert does not apply the same rigorous standards as would be applicable in the practice of his specialty to the opinions of his report, such opinion cannot be presented to a jury.

D. Dr. Hyde's Report Must Also Be Excluded.

Dr. Hyde similarly relies upon PET and SPECT scans done at the University of Montreal and the University of California, Irvine in support of his diagnosis of myalgic encephalomyelitis. For the same reasons as set forth above, this opinion must also be excluded.

Dr. Hyde testified in deposition that Mr. Jeffries' SPECT scans revealed a vasculitis pattern. He went on to state, however, that he could not identify the cause of the vasculitis. Aside the fact that he is admitting his scan does not do what he wants it to do, vasculitis is not a commonly accepted diagnosis that can be made from a SPECT scan. As such, Dr. Hyde's opinion on this point must be excluded.

Dr. Hyde also admits that he is not an expert with regard to the interpretation of PET and SPECT scans. *See* Exhibit C, relevant pages of Hyde deposition at p. 56. Dr. Hyde acknowledged that he would defer to a neuroradiologist as to whether the SPECT scan is reliable in the diagnosis of vasculitis and could not identify any medical resource that would support reliability. *See id.* at p. 8. Finally, Dr. Hyde acknowledged that there is not enough scan research in North American to make the supposition that a PET or SPECT scan is appropriate for the diagnosis of chronic fatigue and that under current scientific standards, the use of PET and/or SPECT scans are not generally accepted as appropriate for the diagnosis of chronic fatigue. Like Dr. Pretorius' opinion, Dr. Hyde's reliance on SPECT scans to support his diagnosis of an autoimmune-disorder must be excluded.

III. CONCLUSION

The report of Dr. Pretorius must be excluded in its entirety. PET and SPECT scans cannot be used scientifically to diagnose the presence or absence of chronic fatigue, depression, somatoform disorder, cerebritis, encephalomyelitis or vasculitis. These diagnoses can only be

supported by the clinical evaluation of a neuropsychologist and neuropsychological testing, such as was performed by Dr. Hartings. The report of Dr. Hyde must also be excluded. Dr. Hyde himself admits that the use of PET and SPECT scans is not scientifically supported. These opinions are not reliable, are not based in scientific fact and therefore must be excluded under *Daubert*.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been filed with the Court by electronic means on this 12th day of December 2003. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

s/Peter M. Burrell
Peter M. Burrell, Esq.

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